# PARTIAL-BIRTH ABORTIONS/Hearings on Trade & Prescription Drugs

**SUBJECT:** **Partial-Birth Abortion Ban Act of 1995 . . . H.R. 1833. Smith (for DeWine/Dodd) second-degree perfecting amendment No. 3088 to the Pryor amendment No. 3082.**

## ACTION: MOTION TO TABLE FAILED, 48-49

**SYNOPSIS:** As introduced, H.R. 1833, the Partial-Birth Abortion Ban Act of 1995, will prohibit partial-birth abortions.

An affirmative defense will be provided if the physician reasonably believes a partial-birth abortion is necessary to save the life of the mother and no other procedure will suffice for that purpose. The term "partial-birth abortion" will be defined as an abo rtion "in which the person performing the abortion partially vaginally delivers the living fetus before killing the fetus and completing the delivery."

The Pryor amendment would amend current law to permit generic drug manufacturers to make drugs that have had their patents extended as a result of the Uruguay Round on the General Agreement on Tariffs and Trade (GATT) during those drugs' extension periods. Royalties would be paid to the patent holders.

**The Smith (for DeWine/Dodd) perfecting amendment** would strike the substance of the Pryor amendment and would substitute in lieu thereof language expressing the sense of the Senate that the Judiciary Committee should hold a hearing on the General Agreement on Tariffs and Trade as it relates to patent protection for pharmaceuticals.

Debate was limited by unanimous consent. Following debate, Senator Pryor moved to table the DeWine/Dodd amendment. Generally, those favoring the motion to table opposed the amendment; those opposing the motion to table favored the amendment.

NOTE: Following the vote, the Pryor amendment was withdrawn.

**Those favoring** the amendment contended:

The issue addressed by the underlying Pryor amendment is much more complex than our colleagues would have us believe. They are trying to rush this issue through the Senate on this unrelated bill without honestly acknowledging that many experts on this area

(See other side)

**YEAS (48)**

| Republicans (12 or 23%) | Democrats (36 or 80%) | |
|---|---|---|
| Bond | Akaka | Heflin |
| Brown | Baucus | Inouye |
| Chafee | Bingaman | Kennedy |
| Cohen | Boxer | Kerrey |
| Hatfield | Bradley | Kerry |
| Jeffords | Breaux | Kohl |
| Kassebaum | Bryan | Leahy |
| Lugar | Bumpers | Levin |
| McCain | Byrd | Mikulski |
| Pressler | Conrad | Murray |
| Roth | Daschle | Nunn |
| Snowe | Dorgan | Pryor |
| | Exon | Reid |
| | Feingold | Robb |
| | Feinstein | Rockefeller |
| | Ford | Sarbanes |
| | Glenn | Simon |
| | Graham | Wellstone |

**NAYS (49)**

| Republicans (40 or 77%) | | Democrats (9 or 20%) |
|---|---|---|
| Abraham | Hatch | Biden |
| Ashcroft | Helms | Dodd |
| Bennett | Hutchison | Harkin |
| Burns | Inhofe | Hollings |
| Campbell | Kempthorne | Johnston |
| Coats | Kyl | Lautenberg |
| Cochran | Lott | Lieberman |
| Coverdell | Mack | Moseley-Braun |
| Craig | McConnell | Pell |
| D'Amato | Murkowski | |
| DeWine | Nickles | |
| Dole | Santorum | |
| Domenici | Shelby | |
| Faircloth | Smith | |
| Frist | Specter | |
| Gorton | Stevens | |
| Gramm | Thomas | |
| Grams | Thompson | |
| Grassley | Thurmond | |
| Gregg | Warner | |

**NOT VOTING (1)**

| Republicans (0) | Democrats (1) |
|---|---|
| | Moynihan-[2] |

**LIVE PAIRS(1):**

**PRESENT AND GIVING:** **RECEIVING:**
Jeffords (PN) . . . . . Gramm (PY)

**EXPLANATION OF ABSENCE:**
1—Official Buisiness
2—Necessarily Absent
3—Illness
4—Other

**SYMBOLS:**
AY—Announced Yea
AN—Announced Nay
PY—Paired Yea
PN—Paired Nay

of patent law strongly believe that the Pryor amendment would harm prescription drug consumers, would harm the pharmaceutical industry, and would do serious damage to the Uruguay Round trade agreement's patent protection provisions, thereby eroding patent protection for all U.S. patented products. We believe that detailed hearings on this matter would bring these points out for all Senators. Accordingly, we have offered the DeWine/Dodd substitute amendment to express the sense of the Senate that the Judiciary Committee, which has jurisdiction over patent issues, should hold hearings on this matter. The Chairman of the Judiciary Committee has assured us that he will schedule such hearings.

We believe that hearings will show that the failure to change patent protection law for drugs was not a mistake; that law was deliberately left unchanged. The patenting of drugs differs from the patenting of other products because of the lengthy approval process involved and because of the cost of developing a new product. Before 1984, the approval process created difficulties for both new product manufacturers and the generic drug companies that produce their products after their patents expire. The Food and Drug Administration is supposed to approve or disapprove a patent application for a new drug within 180 days, but it usually takes much longer than that amount of time. Before 1984, it took generic companies 2 to 3 years to gain approval of their copies of drugs once the patents on those drugs expired, but, with the passage of the Hatch/Waxman Act (the Patents Term Restoration and Drug Price Competition Act), that time has been cut down to almost instant approval. The reason is that generic drug companies, unlike any other companies in America, were given the right to use the original data that was used by the companies that developed the drugs they copied. New drug manufacturers, that spend an average of $350 million and take an average of 12 years to develop a new drug, and that only succeed in patenting 20 percent of the drugs they develop, have to let generic companies use their research for free. Companies that produce new drugs, of course, still face a lengthy approval process. Under the terms of the Uruguay Round, that approval process time will eat into their 20-year patent terms because it will run from the date of application instead of the date of issuance.

The portion of the Uruguay Round dealing with patents, the Intellectual Property Agreement (TRIPS), is the first large international agreement to protect intellectual property rights. In many countries, such rights have been virtually non-existent. American industries consequently have lost tens of billions of dollars in foreign sales, and they have lost huge sums domestically as well due to the sale of imported, pirated products. Many countries that signed on to the TRIPS agreement would happily back out of it. Passing the Pryor amendment would give them the excuse they need. The agreement allows protections such as are in the Pryor amendment when a country signs on to the agreement, but not after. If the United States, which is the country that fought for patent protection, became the first country to weaken that protection to protect one industry, the whole TRIPS agreement would unravel. The United States may experience a very short-term gain from the sale of a few generic prescription drugs by domestic companies, but in the long-term the result of approving this amendment would be disastrous.

We are aware that some trade experts, including in the Clinton Administration, contend that this change would not prove harmful, and we are very willing to listen to their views; perhaps they may persuade us that we are wrong. Those of our colleagues who are convinced that we are wrong should be willing to defend their position in hearings. Rushing through an amendment on an issue that may have such enormous consequences before having a chance to hear expert testimony from both sides would be a terrible mistake. Therefore, we strongly support adoption of the DeWine/Dodd amendment.

**Those opposing** the amendment contended:

Under the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) the signatory nations agreed to 20-year protection for patents starting from the filing date for patents. To conform to this international agreement, the United States changed its patent protection law from 17 years from the issuance of a patent to this new standard. Congress then gave existing patent holders the right to either remain under the old standard or to accept the new standard. As a result, some patent holders gained up to 3 years additional patent protection. For manufacturers who were preparing to make products on which patents were about to expire this extension created a severe problem--after investing often millions of dollars to begin production, they were being told that they could not begin for up to three years. To be fair to such manufacturers, Congress also agreed that generic manufacturers could make products for which patents were extended as long as they paid a royalty to the patent holders. However, in making conforming amendments to existing laws to implement this agreement, Congress made a mistake. It failed to change the law as it applied to drugs. As a result, prescription drug manufacturers that hold patents are receiving a windfall that no other patent holders are receiving. For some prescription drugs such as Zantac, this windfall is enormous. Consumers have to pay up to 3 times as much for patent-protected drugs, meaning that drug companies make billions of dollars in extra profits. In fairness to generic drug manufacturers and in fairness to consumers, the underlying Pryor amendment would correct Congress' mistake. According to the Clinton Administration, the failure to provide this protection was an oversight, and, in our reading of the TRIPS agreement, changes of the type advocated by the Pryor amendment were clearly anticipated. The Pryor amendment would not make a permanent change; it would only make a transitional change to be fair to generic drug manufacturers. The issue is clear--hearings are not necessary. We therefore urge our colleagues to vote against the DeWine/Dodd amendment, and in favor of the underlying Pryor amendment.